



DEPARTMENT OF VETERANS AFFAIRS
OFFICE OF INSPECTOR GENERAL

Office of Healthcare Inspections

VETERANS HEALTH ADMINISTRATION

Delayed Radiology Test
Reporting at the Dwight D.
Eisenhower VA Medical
Center

Leavenworth, Kansas

VA Eastern Kansas Health
Care System



The mission of the Office of Inspector General is to serve veterans and the public by conducting effective oversight of the programs and operations of the Department of Veterans Affairs through independent audits, inspections, reviews, and investigations.

In addition to general privacy laws that govern release of medical information, disclosure of certain veteran health or other private information may be prohibited by various federal statutes including, but not limited to, 38 U.S.C. §§ 5701, 5705, and 7332, absent an exemption or other specified circumstances. As mandated by law, the OIG adheres to privacy and confidentiality laws and regulations protecting veteran health or other private information in this report.

**Report suspected wrongdoing in VA programs and operations
to the VA OIG Hotline:**

www.va.gov/oig/hotline

1-800-488-8244



Executive Summary

The VA Office of Inspector General (OIG) conducted a healthcare inspection in response to a complainant's allegations regarding delays in a patient's lung cancer diagnosis and the reporting of an abnormal radiology test. The OIG also reviewed patients' electronic health records to determine the extent of delays in communicating abnormal test results and evaluate the contributory causes of the delays at the Dwight D. Eisenhower VA Medical Center, Leavenworth, Kansas (system).

In November 2017, the OIG received and reviewed the allegations:

- Providers failed to diagnose a patient in a timely manner.
- Providers failed to communicate with a patient concerning the possibility of an abnormal computed tomography scan.
- A provider falsely documented in a patient's electronic health record that the patient was "now willing to have test/interventions done." The patient never refused the test or intervention, and neither were offered to the patient to refuse.

The OIG requested that the system review the allegations and provide documentation to support the response. The system substantiated the three allegations and sent action plans regarding the identified deficiencies. OIG staff reviewed this evidence and determined it sufficiently addressed the allegations.

During the system's review, the Quality Manager received additional allegations:

- The next of kin was not consulted for palliative care.
- The next of kin was not contacted after the patient's death.
- A chaplain did not visit the patient.

The OIG performed an independent review of the patient's electronic health record and did not substantiate the three additional allegations. The OIG found that the patient named two next of kin, one of whom was present for palliative care decisions and at the time of the patient's death. Additionally, the patient and family were visited by a chaplain.

In February 2018, the OIG followed up with the system for documentation related to administrative (supervisory) review, actions taken regarding possible documentation falsification including a peer review for the providers involved, a copy of the institutional disclosure, and a copy of the mandatory view alert list. In March 2018, the system partially responded to the request. In April, the OIG requested further clarification of the system's response.

In late April 2018, the OIG concluded that portions of the System Quality Manager's response were incomplete. The OIG opened a healthcare inspection to further review the delay in the patient's diagnosis and care to determine the extent of the system's delays in communicating abnormal test results and to evaluate the following contributory causes of the delays:

1. Providers' failure to accept or acknowledge view alerts that may have led delays in diagnoses and reporting of those diagnoses to patients.
2. System leaders' failure to update the system policy to comply with VHA requirements for the communication of test results.
3. System managers' failure to conduct peer reviews as required by VHA and system policy.

There were delays in providers reporting radiology test results and diagnoses to patients; however, the OIG could not determine if the delays were due to missed view alerts. System providers failed to communicate test results needing follow up within the timeframe required by VHA. Additionally, the system policy for communication of test results had not been updated at the time the patient was seen and indicated all test results should be communicated to patients within 14 days. However, VHA requires that test results needing follow-up should be communicated to patients in seven days. Radiologists did not receive training for the new national diagnostic codes or the software that generates view alerts. An administrative investigation should have been completed as required by VA. The system failed to identify a patient incident that should have triggered a peer review as required by VHA and system policy. Additionally, an institutional disclosure was not completed for the patient as required by VHA.

The OIG made five recommendations related to communicating test results, training radiologists, initiating a peer review, conducting an administrative investigation, and initiating an institutional disclosure.

Comments

The Veterans Integrated Service Network and System Directors concurred with the recommendations and provided acceptable action plans. (See Appendixes A–B, pages 16–20 for the comments.) The OIG considers all recommendations open and will follow up on the planned actions until they are completed.



JOHN D. DAIGH, JR., M.D.
Assistant Inspector General
for Healthcare Inspections

Contents

Executive Summary	i
Abbreviations	iv
Introduction	1
Scope and Methodology	4
Patient Case Summary	6
Inspection Results	9
Issue 1: Communicating Test Results	9
Issue 2: System Policy	10
Issue 3: System Response	11
Conclusion	14
Recommendations 1–5	15
Appendix A: VISN Director Comments	16
Appendix B: System Director Comments	17
OIG Contact and Staff Acknowledgments	21
Report Distribution	22

Abbreviations

CT	computed tomography
EHR	electronic health record
OIG	Office of Inspector General
PCP	primary care provider
VHA	Veterans Health Administration
VISN	Veterans Integrated Service Network
VistA	Veterans Health Information Systems and Technology Architecture



Introduction

Purpose

The VA Office of Inspector General (OIG) conducted a healthcare inspection in response to a complainant's allegations regarding delays in a patient's lung cancer diagnosis and the reporting of an abnormal radiology test. The OIG also reviewed patients' electronic health records to determine the extent of delays in communicating abnormal test results and evaluate the contributory causes of the delays at the Dwight D. Eisenhower VA Medical Center, Leavenworth, Kansas (system).

Background

The system is part of Veterans Integrated Service Network (VISN) 15 and offers a wide range of inpatient and outpatient services with a focus on primary and secondary care, psychiatric treatment, and extended care. The system's catchment area covers 39 counties in Kansas and Missouri, providing care to approximately 36,000 veterans. The system delivers healthcare through the Dwight D. Eisenhower VA Medical Center in Leavenworth, Kansas, the Colmery-O'Neil VA Medical Center in Topeka, Kansas, nine community based outpatient clinics, community living centers, and a domiciliary.¹ Medical school affiliations include the University of Kansas and the University of Missouri at Kansas City, Missouri.

Communication of Test Results

Veterans Health Administration (VHA) policy states that each ordering provider or designee is responsible for initiating appropriate clinical action and follow-up for any orders that they have placed. The provider or designee must document any communication and subsequent clinical actions in the patient's electronic health record (EHR) in response to critical, urgent, and clinically significant test results that require therapeutic intervention or action. Test results requiring action, such as abnormal results, must be communicated by the ordering provider or designee to patients no later than seven calendar days from when the results are available. Test results not requiring action, such as normal results, must be communicated by the ordering provider to patients no later than 14 days from the date they are available to the provider.²

¹ The Dwight D. Eisenhower VA Medical Center and the Colmery-O'Neil VA Medical Center are part of the VA Eastern Kansas Health Care System.

² VHA Directive 1088, *Communicating Test Results to Providers and Patients*, October 7, 2015.

View Alerts

“‘View Alerts’ are Computerized Patient Record System notifications to providers about clinical information.”³ View alerts appear with results of tests such as radiology scans. These alerts can be listed as moderate or high importance. There are many mandatory alerts that cannot be turned off by providers. However, there are optional view alerts that can be turned on or off based on provider preferences.

VHA requires that

... facilities follow practices and procedures to better manage view alerts related to test results.⁴ [View alerts] are the most widely used method for asynchronous communication⁵ of test results from diagnostic providers to ordering providers or designees. To ensure that [view alerts] are effective, responded to in a timely manner, and do not create unnecessary information burdens on ordering providers or designees, facilities should evaluate the numbers and types of [view alerts] providers are receiving and use mandatory [view alerts] judiciously.⁶

In 2017, the VA Deputy Under Secretary for Health for Operations and Management released a memo indicating that “due to excessive view alerts, providers can miss critical test results, resulting in patient safety risks and increased provider burnout.”⁷

Peer Review

Peer Review is a process to evaluate the performance of health care professionals. It is completed by health care staff, individually or in a group, to improve quality of care and determine if health care resources are utilized appropriately. Peer review for quality management is required to be confidential and is intended to be non-punitive. Peer review can also be for review of clinical practice, tort claims, and National Practitioner Data Bank reporting. Ultimately, the intention of peer review is to provide immediate or long-term improvements in care, which contribute to better patient outcomes.

³ VHA Memorandum for View Alerts Optimization Program, Office of the Deputy Under Secretary for Health for Operations and Management, March 8, 2017.

⁴ VHA Directive 1088.

⁵ Asynchronous communication is “the exchange of messages, such as among the hosts on a network or devices in a computer, by reading and responding as schedules permit rather than according to some clock that is synchronized for both the sender and receiver or in real time.” www.linfo.org/asynchronous.html. (The website was accessed on August 15, 2018.)

⁶ VHA Directive 1088.

⁷ VHA Memorandum. *View Alerts Optimization Program*, March 8, 2017.

VHA requires that a peer review is initiated when members of leadership have concerns about quality of care or when patients experience care that has negative or unexpected consequences to determine if the care was appropriate.⁸

Institutional Disclosure

VHA defines an institutional disclosure of adverse events as

... a formal process by which facility leader(s) together with clinicians and others, as appropriate, inform the patient or the patient's personal representative that an adverse event has occurred during the patient's care that resulted in, or is reasonably expected to result in, death or serious injury, and provide specific information about the patient's rights and recourse.⁹

Adverse events are "untoward incidents or other occurrences of harm or potential harm directly associated with care or services to Veterans."¹⁰

Allegations

In November 2017, the OIG received and reviewed a complainant's allegations:

- Providers failed to diagnose a patient in a timely manner.
- Providers failed to communicate with a patient concerning the possibility of an abnormal computed tomography (CT) scan.
- A provider falsely documented in a patient's electronic health record that the patient was "now willing to have test/interventions done." The patient never refused the test or intervention, and neither were offered to the patient to refuse.

The OIG requested that the system review the allegations and provide documentation to support the response. The system substantiated the three allegations and sent action plans regarding the identified deficiencies. OIG staff reviewed this evidence and determined it sufficiently addressed the allegations.

During the system's review, the Quality Manager received additional allegations:

- Next of kin was not consulted for palliative care,

⁸ VHA Directive 2010-025, *Peer Review for Quality Management*, June 3, 2010.

⁹ VHA Handbook 1004.08, *Disclosure of Adverse Events to Patients*, October 2, 2012, this handbook was in effect at the time of the events that transpired for this inspection. The 2012 handbook was rescinded and replaced by VHA Directive 1004.08, *Disclosure of Adverse Events to Patients*, October 31, 2018. The 2018 directive "Removes the requirement that VA medical facility leaders must confer with District Chief Counsel prior to initiating an institutional disclosure. Consultation with District Chief Counsel is now at the discretion of VA medical facility leadership."

¹⁰ VHA Handbook 1004.08; VHA Directive 1004.08.

- The next of kin was not contacted after the patient's death, and
- A chaplain did not visit the patient.

The OIG performed an independent review of the patient's EHR and did not substantiate the three additional allegations. The OIG found that the patient named two next of kin, one of whom was present for palliative care decisions and at the time of the patient's death. The OIG also found that the patient and family were visited by a chaplain.

In February 2018, the OIG followed up with the system for documentation related to administrative (supervisory) review, actions taken regarding possible documentation falsification including a peer review for the providers involved, a copy of the Institutional Disclosure, and a copy of the mandatory view alert list. In March 2018, the system partially responded to the OIG's request. In April, the OIG requested further clarification of the system's response.

In late April 2018, the OIG determined that portions of the system quality manager's response were incomplete. The OIG opened a healthcare inspection to further review the delay in the patient's diagnosis and care to determine the extent of the system's delays in communicating abnormal test results, and to evaluate the following contributory causes of the delays:

1. Providers' failure to accept or acknowledge view alerts that may have led delays in diagnoses and reporting of those diagnoses to patients.
2. System leaders' failure to update the system policy to comply with VHA requirements for the communication of test results.
3. System managers' failure to conduct peer reviews as required by VHA and system policy.

Scope and Methodology

The OIG initiated the inspection on April 19, 2018, and conducted a site visit from June 4–7, 2018.

The OIG interviewed the system's Chief of Staff, Chief of Radiology, Chief of Ambulatory Care, Chief Quality Management Officer, and other key staff, including the provider who ordered the CT scan, the results of which were alleged to have not been communicated. Additionally, the OIG interviewed VISN 15 and VA Central Office staff knowledgeable of the topics covered in this review.

The OIG reviewed VHA directives, handbooks, memoranda, guidelines, and requirements; system policies; standard operating procedures, EHRs, radiology coding reports, and data from the Veterans Health Information Systems and Technology Architecture (VistA).¹¹

In the absence of current VA or VHA policy, the OIG considered previous guidance to be in effect until superseded by an updated or recertified directive, handbook, or other policy document on the same or similar issue(s).

The OIG substantiates an allegation when the available evidence indicates that the alleged event or action more likely than not took place. The OIG does not substantiate an allegation when the available evidence indicates that the alleged event or action more likely than not did not take place. The OIG is unable to determine whether an alleged event or action took place when there is insufficient evidence.

The OIG conducted the inspection in accordance with *Quality Standards for Inspection and Evaluation* published by the Council of the Inspectors General on Integrity and Efficiency.

¹¹ VistA provides an “integrated inpatient and outpatient EHR for VA patients, and administrative tools to help VA deliver medical care to veterans.” <https://www.data.va.gov/dataset/veterans-health-information-systems-and-technology-architecture-vista>. (The website was accessed on August 8, 2018.)

Patient Case Summary

The sexagenarian patient received both primary and specialty care services at the system. The patient's medical history included substance use disorder, opioid dependence, mood disorder, insomnia, anxiety, chronic obstructive pulmonary disease, and many years of tobacco use. The patient saw a psychiatrist monthly as scheduled.

A primary care provider (PCP 1) saw the patient for multiple medical issues for seven months in 2015. In fall 2015, the patient presented for a scheduled appointment with PCP 1; complained of a cough and phlegm; and denied shortness of breath, chest pain, or weight loss. A previously ordered chest x-ray to check for pulmonary fibrosis was performed and read on the same day of the PCP 1 appointment, which noted fibrosis, emphysema, and the development of pneumonia.¹² PCP 1 documented the discussion of results and prescription of antibiotics to treat the patient's possible pneumonia the same day as the examination.

Nine days after the chest x-ray was completed, PCP 1 ordered a CT scan of the chest that was performed approximately three weeks later.¹³ The radiologist documented that tuberculosis or malignancy should be considered and coded this image as "abnormal." The radiologist documented "further evaluation with a CT/Positron Emission Tomography scan should be of benefit."¹⁴ There was no documentation in the EHR that the reading radiologist contacted any provider with the result. There was no documentation that PCP 1 contacted the patient about results of this CT scan.

In early 2016, a medical support assistant noted a cancelled chest x-ray in the patient's EHR. The request expired after 60 days; documented instructions were to enter a new request if the exam

¹² Pulmonary Fibrosis is "a lung disease that occurs when lung tissue becomes damaged and scarred." <https://www.mayoclinic.org/diseases-conditions/pulmonary-fibrosis/symptoms-causes/syc-20353690>. (The website was accessed on August 9, 2018.); Emphysema is "a condition of the lung marked by abnormal enlargement of the alveoli with loss of pulmonary elasticity that is characterized especially by shortness of breath and may lead to impairment of heart action." <https://www.merriam-webster.com/dictionary/emphysema>. (The website was accessed on August 9, 2018.); Pneumonia is "an acute disease that is marked by inflammation of lung tissue accompanied by infiltration of alveoli and often bronchioles with white blood cells (such as neutrophils) and fibrinous exudate, is characterized by fever, chills, cough, difficulty in breathing, fatigue, chest pain, and reduced lung expansion, and is typically caused by an infectious agent." <https://www.merriam-webster.com/dictionary/pneumonia>. (The website was accessed on August 9, 2018.)

¹³ CT is "radiography in which a three-dimensional image of a body structure is constructed by computer from a series of plane cross-sectional images made along an axis." <https://www.merriam-webster.com/dictionary/computerized%20tomography>. (The website was accessed on August 1, 2018.)

¹⁴ A Positron Emission Tomography scan is "a sectional view of the body constructed by positron-emission tomography." <https://www.merriam-webster.com/dictionary/PET%20scan>. (The website was accessed on August 1, 2018.)

was still indicated. PCP 1 acknowledged the message the following day. However, no provider ordered any additional radiologic studies.

In fall 2016, the covering provider (PCP 2) saw the patient who presented to the clinic with sinus and chest congestion. PCP 2 ordered a chest x-ray that was conducted on the same day. The reading radiologist compared the image to a fall 2015 chest x-ray and documented an abnormality, possible malignancy, in the new chest x-ray located at the same site as the previous abnormality. PCP 2 discussed the results of the abnormal x-ray with the patient the same day.

The following day, PCP 1 ordered a CT scan and biopsy of the chest, and it was performed approximately two weeks later.¹⁵ The CT scan reading identified a large mass in the left lung and enlarged lymph nodes. The reading radiologist stated that between the current scan and the previous scan in late 2015, “the mass had enlarged from 2 x 3 cm [centimeters] to 3.6 x 5 cm.”

The patient received the diagnosis from PCP 1 of squamous cell carcinoma with possible metastatic disease five days after the CT scan and biopsy.¹⁶ The patient was diagnosed with Stage IIIA squamous cell lung cancer with the possibility of metastatic disease 10 months after the initial CT scan.¹⁷

In fall 2016, PCP 1 called the patient and documented the patient “is now willing to have these tests/interventions done.” However, between late 2015 and fall 2016, there was no EHR documentation that system staff contacted the patient about an abnormal test result or that the patient was offered or declined tests and interventions. After notification of the diagnosis, the patient required and received medication for anxiety.

¹⁵ Biopsy is “the removal and examination of tissue, cells, or fluids from the living body.” <https://www.merriam-webster.com/dictionary/biopsy>. (The website was accessed on August 9, 2018.)

¹⁶ Squamous cell carcinoma is “an uncontrolled growth of abnormal cells arising from the squamous cells in the epidermis, the skin’s outermost layer.” <https://www.skincancer.org/skin-cancer-information/squamous-cell-carcinoma>. (The website was accessed on August 1, 2018.); Metastatic disease (cancer) is “the medical term for cancer that spreads to a different part of the body from where it started.” <https://www.cancer.net/navigating-cancer-care/cancer-basics/what-metastasis>. (The website was accessed on August 1, 2018.)

¹⁷ In Stage IIIA Cancer has “spread to lymph nodes on the same side of the chest as the tumor.” NCI Dictionary of Cancer Terms. <https://www.cancer.gov/publications/dictionaries/cancer-terms/def/stage-iiia-non-small-celllung-cancer>. (The website was accessed on August 16, 2018).

Starting in late fall 2016, the patient was consulted to hematology/oncology and radiation oncology and the patient's case was presented to the Tumor Board.¹⁸ The patient received radiation therapy and chemotherapy. In early 2017, the patient was hospitalized due to complications of the therapy. The Tumor Board members determined that the patient was not a surgical candidate, and the patient received additional radiation and chemotherapy that was completed in late spring 2017.

In early summer 2017, the patient presented to the system's emergency department with two weeks of progressive shortness of breath. The patient was admitted to the Intensive Care Unit, diagnosed with pneumonia versus radiation pneumonitis, and hypoxemia.¹⁹ ICU staff treated the patient with antibiotics, steroids, respiratory therapy, and oxygen support; however, the patient's pulmonary status worsened. The palliative care provider discussed end-of-life care with the patient, and the patient subsequently chose not to be resuscitated.²⁰ The patient died in mid-summer 2017.

¹⁸ Hematology is "a medical science that deals with the blood and blood-forming organs." <https://www.merriam-webster.com/dictionary/hematology>. (The website was accessed on August 1, 2018.). Oncology is "a branch of medicine concerned with the prevention, diagnosis, treatment, and study of cancer." <https://www.merriam-webster.com/dictionary/oncology>. (The website was accessed on August 1, 2018.); Radiation Oncology is a radiology specialty that specializes in treating all types of cancer using a variety of forms of radiation. Radiation therapy uses carefully targeted and regulated doses of high-energy radiation to kill cancer cells. <https://www.mayoclinic.org/departments-centers/radiation-oncology/sections/overview/ovc-20188591>. (This website was accessed on October 29, 2018.); "Tumor boards are meetings where specialists from surgery, medical oncology, radiation oncology, radiology, genetics, and pathology collaboratively review a patient's condition and determine the best treatment plan." <https://stanfordhealthcare.org/medical-clinics/cancer-center/cancer-tumor-boards.html>. (The website was accessed on October 30, 2018.)

¹⁹ Radiation Pneumonitis is "inflammation of the lung caused by radiation therapy to the chest." <http://www.cancer.ca/en/cancer-information/diagnosis-and-treatment/managing-side-effects/radiation-pneumonitis/?region=on><http://www.cancer.ca/en/cancer-information/diagnosis-and-treatment/managing-side-effects/radiation-pneumonitis/?region=on>. (The website was accessed on August 9, 2018.); Hypoxemia is "a deficiency of oxygenation of the blood." <https://www.merriam-webster.com/dictionary/hypoxemia>. (The website was accessed on August 9, 2018.)

²⁰ Palliative care is "medical and related care provided to a patient with a serious, life-threatening, or terminal illness that is not intended to provide curative treatment but rather to manage symptoms, relieve pain and discomfort, improve quality of life, and meet the emotional, social, and spiritual needs of the patient." <https://www.merriam-webster.com/medical/palliative%20care>. (The website was accessed on August 1, 2018.)

Inspection Results

Issue 1: Communicating Test Results

View Alerts

The OIG determined there were delays in communicating radiology test results and diagnoses to patients. VHA policy requires that test results needing follow-up are communicated to patients within seven days of the availability of the test results.²¹ The system policy for communication of test results at the time the patient was seen indicated that all test results were to be communicated to patients within 14 days.²²

Communication of radiology test results from the radiologist to the ordering provider and then to the patient involves multiple steps. The radiologist interprets the image and assigns a diagnostic code. A clinical applications coordinator is then responsible for making the code active in VistA to generate a view alert to the ordering provider. The ordering provider must select the assigned code to be active from their notification settings to receive the intended view alert, unless the assigned code is designated as mandatory by VISN 15.

The system's practice was to review cases with a diagnostic code 32, which indicates a possible malignancy needing follow-up. The Risk Manager then contacts the providers who have not yet reported the results to patients. The radiology finding for the patient was a possible malignancy needing follow up. However, the interpretation was not assigned a code 32. Therefore, the system's practice did not include a review of the patient's case. The OIG reviewed interpretations assigned a code 32 from October 1, 2015, through March 31, 2017, and determined that 45 out of 249 (18 percent) of patients reviewed did not receive communication of their test results within the required timeframe and/or imaging results were not documented in their EHRs. The OIG reviewed EHRs of the 45 patients who did not have documentation of receiving notification of abnormal test results within seven days. There was evidence of ongoing evaluation and care, and the patients reviewed did not suffer adverse outcomes related to the delays.

Acknowledging View Alerts

The OIG was unable to determine if providers failed to accept or acknowledge view alerts. VistA reports were reviewed from May 1, 2017, through May 31, 2018, to determine the timeliness between view alert deployment and provider review of those alerts. The data set provided fields to collect information on the status of view alerts and dates view alerts were generated,

²¹ VHA Directive 1088.

²² System Policy Memorandum 111-02, *Ordering and Reporting Test Results*, September 12, 2014.

acknowledged, acted on, manually deleted, and autodeleted. The OIG was unable to determine if all providers accepted their view alerts due to blank data fields in the collection and storage of this data. For example, the data field for “status” was entirely blank, and the fields with dates for tracking view alerts also had many blank fields. Additionally, an interviewee stated that all view alert data in VISN 15 prior to December 2016 were lost due to a system migration.

VHA requires that VA medical facilities follow practices and procedures to ensure the effectiveness and timeliness of providers’ review of view alerts while not creating unnecessary information burdens on ordering providers. Additionally, facilities should review the amount and type of view alerts and use mandatory view alerts judiciously.²³

The VISN 15 Medical Informatics Officer stated that a project was completed in December 2015 to help providers better manage their view alerts and standardize mandatory alerts. However, the OIG interviewed numerous leaders and staff who repeatedly cited an unnecessary view alert burden that they felt impacted patient care. In May 2018, VISN 15 leaders converted from locally established codes to the national radiology diagnostic codes, which reduced the number of mandatory view alerts. Several system staff members stated that radiologists do not receive formal training in the use of the software that generates view alerts. Furthermore, there was no training for the radiologists after the conversion to national codes. System staff said they did not know which codes generate a view alert. There was no system policy or standard procedure for coding results to trigger a view alert. Therefore, communication of test results was not consistent for diagnostic providers.

The VHA National Center for Patient Safety sent an April 9, 2018, patient safety alert to all VHA facilities, indicating “differences between diagnostic codes in the VistA radiology package and voice recognition software applications may result in failure to trigger a [view alert] to the ordering provider.” This patient safety alert required leaders at each facility to complete a system review and implement any necessary corrective action. The system Patient Safety Manager was required to document that leaders had reviewed and implemented the required action by May 22, 2018. The OIG received confirmation indicating the system complied with the safety alert follow-up actions.

Issue 2: System Policy

The system did not update their policy to comply with VHA requirements for the communication of test results.²⁴

²³ VHA Directive 1088.

²⁴ VHA Directive 1088.

VHA policy states that all test results requiring action, including laboratory and radiology results, should be communicated by the ordering provider, or designee, to patients no later than seven calendar days from the date on which the results are available.²⁵ System Policy Memorandum 111-02, *Ordering and Reporting Test Results*, September 12, 2014, requires that ordering providers communicate all non-critical results, both abnormal and normal, to patients or their personal representatives within 14 calendar days from the date results are available to the provider.²⁶ The system added a new policy that did not include a timeframe requirement for communication of test results to patients.²⁷ The Chief of Staff acknowledged that the system policy should have been updated, and the Associate Chief of Staff was currently working on updating the policy during the time of the OIG site visit in June 2018.

The OIG determined that the patient did not receive their abnormal test results in the timeframe required by VHA.²⁸ A PCP communicated the possible malignancy result to the patient 288 days after the test was completed. The failure to update system policy in accordance with VHA requirements may have contributed to the patient and others not receiving their test results and diagnoses timely.

Issue 3: System Response

The OIG reviewed the follow-up information provided by the system regarding the administrative supervisory review on documentation falsification, the peer review of the patient's care, responses to additional allegations, and a copy of the institutional disclosure.

Administrative Supervisory Review

The system Quality Manager stated that PCP 1's supervisor was directed by the Chief of Staff to complete an administrative supervisory review. PCP 1's supervisor said the patient was contacted; however, no documentation was entered in the EHR. The supervisor determined that no further action was necessary, and no administrative investigation was warranted. However, the OIG determined that an administrative investigation was warranted based on VA requirements.

²⁵ VHA Directive 1088.

²⁶ System Policy Memorandum 111-02.

²⁷ System Policy Memorandum 115-04, *Reporting Critical and Abnormal Imaging Tests*, April 18, 2016; VHA Directive 1088.

²⁸ VHA Directive 1088.

VA defines eight conditions to be considered when deciding if an administrative investigation board is necessary:

1. Impact of the matter on the facility, VA, government, veterans, and public interests generally, including financial impact
2. Risk of adverse consequences from recurrence
3. Need for objective, expert review and analysis of the matter
4. Seriousness of any suspected misconduct [and/or] neglect
5. Degree to which the cause and essential facts of the matter are known, subject to dispute, or unknown, and the potential for an investigation to determine additional relevant information
6. Need for evidence to support corrective or disciplinary action or claims for or against VA
7. Potential for adverse public, governmental, or media interest
8. Other investigations being conducted into the same or closely related subject matter, and the availability and adequacy of those investigations to meet VA's informational needs²⁹

VA Handbook 0700 states that “Untimely investigations may limit the effectiveness of corrective action and extend or aggravate disruption of VA facilities and missions.” At least three of the VA conditions listed above (items 3, 4, and 6) were applicable to PCP 1 and should have prompted system leaders to consider convening an Administrative Investigation Board.

Peer Review

The system's Peer Review Committee initiated a peer review but did not perform it until after the OIG inquiry.³⁰ The system's Quality Manager learned of the incident during a clinical disclosure to the family, which should have resulted in the initiation of a peer review.³¹

VHA policy requires that a peer review is initiated when members of leadership have concerns about quality of care or when patients experience care that has negative or unexpected consequences to determine if the care was appropriate.³²

²⁹ VA Handbook 0700, *Administrative Investigations*, July 31, 2002.

³⁰ VHA Directive 2010-025; System Policy Memorandum OOB-07, *Protected Peer Review*, December 02, 2013.

³¹ VHA Handbook 1004.08. Clinical disclosure is a process by which the patient's clinician informs the patient or the patient's personal representative, as part of routine clinical care that a harmful or potentially harmful adverse event has occurred during the patient's care; VHA Directive 1004.08. The 2018 directive contains the same or similar language regarding clinical disclosure.

³² VHA Directive 2010-025.

Peer review can result in "...both immediate and long-term improvements in patient care by revealing areas for improvement in the practice of one or multiple providers which contributes to organizational optimal patient outcomes." Failure to conduct a peer review effects the integrity of the quality assurance program.³³

Additional Allegations

The OIG reviewed the system's response to the additional allegations that the next of kin was not contacted after the patient's death, was not consulted for palliative care, and a Chaplain did not visit the patient. The OIG did not substantiate these three additional allegations. The patient named two next of kin, one of whom was present for care decisions and at the time of the patient's death, and the patient and family were visited by a Chaplain.

Institutional Disclosure

An institutional disclosure was not completed for the patient as required by VHA.³⁴ The Quality Manager told the OIG that they did not provide an institutional disclosure to the family because a clinical disclosure was provided on October 19, 2017.

When an adverse event, has resulted in or is reasonably expected to result in death or serious injury, an institutional disclosure must be performed regardless of when the event is discovered. This disclosure is required even if clinical disclosure has already occurred.³⁵

VHA defines adverse events as "untoward incidents or other occurrences of harm or potential harm directly associated with care or services to veterans."³⁶ VHA states that disclosure is warranted for "adverse events that cause death or disability, lead to prolonged hospitalization, require life-sustaining intervention or intervention to prevent impairment or damage (or that are reasonably expected to result in death or serious and/or permanent disability), or that are sentinel events."³⁷ According to system policy, the system Director should ensure "that clinical and institutional disclosures of adverse events are performed openly and promptly with patients

³³ VHA Handbook 1088.

³⁴ VHA Handbook 1004.08. Institutional disclosure (sometimes referred to as an "administrative disclosure") is a formal process by which facility leader(s) together with clinicians and others, as appropriate, inform the patient or the patient's personal representative that an adverse event has occurred during the patient's care that resulted in, or is reasonably expected to result in, death or serious injury, and provide specific information about the patient's rights and recourse; VHA Directive 1004.08. The 2018 directive contains the same or similar language regarding institutional disclosure.

³⁵ VHA Handbook 1004.08; VHA Directive 1004.08.

³⁶ VHA Handbook 1004.08; VHA Directive 1004.08.

³⁷ VHA Handbook 1004.08; VHA Directive 1004.08.

and/or their personal representatives.”³⁸ The OIG determined that the delay in communicating the abnormal CT scan results and the patient’s subsequent death from metastatic lung cancer qualified as an adverse event causing serious harm. An institutional disclosure should have been performed.

Conclusion

There were delays in reporting radiology test results and diagnoses to patients. However, the OIG could not determine whether those delays were due to providers’ missed view alerts because of incomplete evidence. Eighteen percent of the patients reviewed did not receive their abnormal test results within the required timeframe.

The system failed to update the system policy to comply with VHA requirements on the communication of test results, and the current system policy does not include a requirement that test results needing action should be communicated to patients within seven days of their availability.

Radiologists did not receive training for the new national diagnostic codes or the software that generates view alerts.

An administrative investigation, a peer review, and an institutional disclosure should have been completed as required by VHA.

The OIG made five recommendations.

³⁸ System Policy Memorandum 00B-10, *Disclosure of Adverse Events to Patient’s Purpose*, April 7, 2016.

Recommendations 1–5

1. The VA Eastern Kansas Health Care System Director ensures providers communicate abnormal test results to patients and update the VA Eastern Kansas Health Care System policy in accordance with Veterans Health Administration Directive 1088 and monitors for compliance.
2. The VA Eastern Kansas Health Care System Director ensures radiologists receive training for the national diagnostic codes and the software that triggers view alerts.
3. The VA Eastern Kansas Health Care System Director ensures that peer reviews are initiated in accordance with Veterans Health Administration Directive 2010-025 and monitors for compliance.
4. The VA Eastern Kansas Health Care System Director ensures that an administrative investigation of the primary care provider involved in the patient’s care is conducted in accordance with VA Handbook 0700 and takes any action necessary.
5. The VA Eastern Kansas Health Care System Director considers initiating an institutional disclosure consistent with Veterans Health Administration Directive 1004.08 and takes action as necessary.

Appendix A: VISN Director Comments

Department of Veterans Affairs Memorandum

Date: January 23, 2019

From: Director, VA Heartland Network (10N15)

Subj: Healthcare Inspection—Delayed Radiology Test Reporting at the VA Eastern Kansas Health Care System—Dwight D. Eisenhower VA Medical Center, Leavenworth, Kansas

To: Director, Office of Healthcare Inspections (54HL02)
Director, Management Review Service (VHA 10E1D MRS Action)

1. Please find the initial status response for the Delayed Radiology Test Reporting at VA Eastern Kansas Health Care System, Leavenworth KS (Conducted April 2018).
2. I have reviewed and concur with the Medical Center Director's response.
3. Thank you for this opportunity to focus on the continuous performance improvement.
4. For additional questions, please feel free to contact VISN 15 at 816-701-3000.

(original signed by:)

William P. Patterson, MD, MSS

Network Director

VA Heartland Network (VISN 15)

Appendix B: System Director Comments

Department of Veterans Affairs Memorandum

Date: January 22, 2019

From: Director, VA Eastern Kansas Health Care System (589A6/00)

Subj: Healthcare Inspection—Delayed Radiology Test Reporting at the VA Eastern Kansas Health Care System—Dwight D. Eisenhower VA Medical Center, Leavenworth, Kansas

To: Director, VA Heartland Network (10N15)

1. I appreciate the OIG's comprehensive report and efforts to ensure high quality of care for our Veterans.
2. Eastern Kansas is in concurrence with the report as indicated.

(original signed by:)

A. Rudy Klopfer, FACHE

Director/CEO VA Eastern Kansas Health Care System

Comments to OIG's Report

Recommendation 1

The VA Eastern Kansas Health Care System Director ensures providers communicate abnormal test results to patients and update the VA Eastern Kansas Health Care System policy in accordance with Veterans Health Administration Directive 1088 and monitors for compliance.

Concur.

Target date for completion: April 1, 2019

Director Comments

Eastern Kansas Health Care System (EKHCS) is implementing an updated policy for Reporting Critical and Abnormal Imaging test results which will be completed and communicated to staff by 1 March 2019. Compliance monitoring is built into the 2019 OPPE process for all services. The Risk Manager audits codes for abnormal findings per directive. Results from the three processes noted above are reported to the Medical Executive Board.

Recommendation 2

The VA Eastern Kansas Health Care System Director ensures radiologists receive training for the national diagnostic codes and the software that triggers view alerts.

Concur.

Target date for completion: January 9, 2019 - Complete

Director Comments

Radiology Service Line Manager provided training on the national diagnostic codes and software triggers associated with Powerscribe, VISTA, and view alerts on January 9, 2018.

OIG Update: The OIG considers this recommendation open to allow the submission of documentation to support closure.

Recommendation 3

The VA Eastern Kansas Health Care System Director ensures that peer reviews are initiated in accordance with Veterans Health Administration Directive 2010-025 and monitors for compliance.

Concur.

Target date for completion: April 1, 2019

Director Comments

Veterans' Health Administration Directive 2010-025 has been rescinded. The facility's local Peer Review policy is being updated to reflect changes in the recently published Peer Review Directive 1190 dated November 21, 2018. Once the revised policy is approved, applicable staff will be trained on its contents and the requirements for peer review. Compliance with conducting peer reviews will be monitored by the Risk Management Committee and reported to the Medical Executive Board.

Recommendation 4

The VA Eastern Kansas Health Care System Director ensures that an administrative investigation of the primary care provider for the patient's care is conducted in accordance with VA Handbook 0700 and takes any action necessary.

Concur.

Target date for completion: May 3, 2018

Director Comments

We concur with this recommendation and the investigation has already been performed. At the time the OIG Hotline was received (Ref. VA OIG Hotline CA 2018-00980-HL-0727, Feb 9, 2018), the Chief of Staff (COS) and Deputy Chief of Staff (DCOS) initiated a management review which is one type of 'administrative investigation' according to VHA Directive 1190, Peer Review for Quality Management. The management review was conducted as part of a preliminary inquiry (refer to VHA Handbook 0700, Administrative Investigations) to gather information for the convening authority so that they could determine whether a full administrative investigation was needed. In May 2018, the review determined no initiation of an Administrative Investigative Board (AIB) was required. After continued consideration of the concern and continued questions, the results of the reviews were reported to the Medical Center Director by June 12, 2018 who determined that an AIB was not warranted. The COS and DCOS took appropriate action with the provider based upon the results.

OIG Update: The OIG considers this recommendation open to allow the submission of documentation to support closure.

Recommendation 5

The VA Eastern Kansas Health Care System Director considers initiating an institutional disclosure consistent with Veterans Health Administration Directive 1004.08 and takes action as necessary.

Concur.

Target date for completion: April 1, 2019

Director Comments

On October 19, 2017, an interdisciplinary team from EKHCS including the Quality Manager, Chaplain, Veterans Experience Officer, Privacy Officer, and Registered Nurse met face-to-face with the Veteran's adult child and spouse. During this meeting, a full disclosure of the event was given, including: an overview of the event and the care provided; an expression of concern and apology; their right to seek legal advice under the Federal Tort Claims Act, including information on completing an SF 95; contact information for facility staff who could respond to questions regarding the disclosed information; and that a review of care was being conducted. During the meeting, the interdisciplinary team also answered all the family's questions and they verbalized understanding of the events, their options and the process. However, while the facility met almost all of the requirements for an institutional disclosure during the meeting with the Veteran's family, they did not confer with Regional Counsel before the disclosure, nor did they document the disclosure using the CPRS Institutional Disclosure of Adverse Event Note Template. The facility Director found there was confusion on what constituted a clinical disclosure versus an institutional disclosure. The Director elected not to conduct another meeting with the family since the critical aspects of an institutional disclosure were met; rather that additional training on institutional disclosures was needed and would be provided.

OIG Contact and Staff Acknowledgments

Contact For more information about this report, please contact the Office of Inspector General at (202) 461-4720.

Inspection Team Glen Trupp, RN, MHSM, Portfolio Director
Carrie Jeffries, ANP-BC, FACHE, Project Leader
Katherine Gemmell, LCSW, MPH, Team Leader
Jonathan Ginsberg, JD
Patrice Marcarelli, MD
Glenn Schubert, MPH
Christopher White, PT, MHA

Other Contributors Shirley Carlile, BA
Laura Dulcie, BSEE
Jason Reyes, BS
Natalie Sadow, MBA

Report Distribution

VA Distribution

Office of the Secretary
Veterans Health Administration
Assistant Secretaries
General Counsel
Director, VA Heartland Network (10N15)
Director, VA Eastern Kansas Healthcare System - Dwight D Eisenhower VA Medical
Center (589A6/00)

Non-VA Distribution

House Committee on Veterans' Affairs
House Appropriations Subcommittee on Military Construction, Veterans Affairs, and
Related Agencies
House Committee on Oversight and Reform
Senate Committee on Veterans' Affairs
Senate Appropriations Subcommittee on Military Construction, Veterans Affairs, and
Related Agencies
Senate Committee on Homeland Security and Governmental Affairs
National Veterans Service Organizations
Government Accountability Office
Office of Management and Budget
U.S. Senate: Jerry Moran, Pat Roberts
U.S. House of Representatives: Sharice Davids, Ron Estes, Roger Marshall,
Steven Watkins